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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/931,883	08/20/2001	Vaughn Vasil		4041

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VAUGHN SMIDER
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EXAMINER

PADMANABHAN, KARTIC

ART UNIT	PAPER NUMBER
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1641

DATE MAILED: 06/03/2003

4

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/931,883

Applicant(s)

VASIL, VAUGHN

Examiner

Kartic Padmanabhan

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 12 March 2003.
- 2a) ☐ This action is FINAL. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-22 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-22 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 20 August 2001 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved by the Examiner.
- If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
 - ☐ Certified copies of the priority documents have been received in Application No. _____.
 - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.
- 14) ☒ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
- a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892) 4) ☐ Interview Summary (PTO-413) Paper No(s). _____
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948) 5) ☐ Notice of Informal Patent Application (PTO-152)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____ 6) ☐ Other: _____

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DETAILED ACTION

Election/Restrictions

1. Applicant's election with traverse of Group II in Paper No. 3 is acknowledged. Applicant's arguments are persuasive, and the restriction requirement is herein withdrawn. Therefore, claims 1-22 are examined herein.

Information Disclosure Statement

2. The listing of references in the specification is not a proper information disclosure statement. 37 CFR 1.98(b) requires a list of all patents, publications, or other information submitted for consideration by the Office, and MPEP § 609 A(1) states, "the list may not be incorporated into the specification but must be submitted in a separate paper." Therefore, unless the references have been cited by the examiner on form PTO-892, they have not been considered.

Claim Rejections - 35 USC § 112

3. The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.
4. Claims 1-22 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.
5. Claim 1 recites the limitation "the DNA" in line 1 of the claim. There is insufficient antecedent basis for this limitation in the claim. In addition, applicant should begin the claim with "A method" instead of "a method." In addition, it is unclear if the detection step entails

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detecting the immobilized test substance while still immobilized or if it simply requires detecting the once immobilized test substance but not necessarily while still immobilized.

6. Claim 9 recites the limitation "the DSSBP" in line 1 of the claim. There is insufficient antecedent basis for this limitation in the claim. Applicant has not previously referenced this terms in the claims; applicant should maintain consistent terminology throughout the claim set.

7. Claim 12 recites the limitation "the DSSBP modulating activity" in line 1 of the claim. There is insufficient antecedent basis for this limitation in the claim.

8. Claim 12 is rejected as vague and indefinite for the recitation of "capable" because it has been held that the recitation that an element is "capable of" performing a function is not a positive limitation but only requires the ability to so perform. It does not constitute a limitation in any patentable sense. *In re Hutchison*, 69 USPQ 138.

9. Claim 12 is also rejected as vague and indefinite because it does not end in period, which makes it unclear if text was inadvertently omitted or not.

10. Claim 13 is rejected as vague and indefinite because it is unclear if the detection step entails detecting the immobilized test substance while still immobilized or if it simply requires detecting the once immobilized test substance but not necessarily while still immobilized.

11. Claim 22 is rejected as vague and indefinite because it recited claim dependency to claim 9; however, it appears that the claim should depend on claim 19, and is being treated as such in the present action.

Claim Rejections - 35 USC § 102

12. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

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A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

(e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

13. Claims 1-3, 5, 12-15, and 17 are rejected under 35 U.S.C. 102(e) as being anticipated by Crute (US Pat. 5,958,696). The reference discloses a quantitative solid phase helicase assay, wherein a helicase substrate comprising a single stranded nucleic acid polymer hybridized to a labeled helicase reaction product is immobilized onto a solid support. The immobilized substrate is then contacted with a test substance to produce a reaction premix. The test substance is then detected (Col. 12). The solid phase of the reference may be a microtiter plate (Claim 4 of reference). In addition, the extended single-stranded nucleic acid polymer may be made of either RNA or DNA.

14. Claims 1, 3, 5, 7-9, 12-13, 15, 17, and 19-20 are rejected under 35 U.S.C. 102(b) as being anticipated by Giordano et al. (US Pat. 5,705,344). The reference discloses a screening assay for helicase inhibitors, wherein a mixture is formed of a first nucleic acid hybridized to an unlabeled second nucleic acid, a helicase, a nucleoside triphosphate, and a test agent. The first and second nucleic acids may both be DNA. The second nucleic acid is immobilized on a solid substrate, and the amount of label retained on the immobilized second nucleic acid is measured as an indication of helicase modulation (Claim 1). Helicases are enzymes that may function in various cellular functions, including DNA repair. The candidate helicase sample are typically cellular or nuclear extracts (Col. 7, lines 50-56). Detection may be carried out by coating the substrate with an antibody (claim 5 of reference).

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15. Claims 1-3, 5, 7, 12-15, and 17 are rejected under 35 U.S.C. 102(b) as being anticipated by Shi et al. (US Pat. 5,919,626). The reference discloses the attachment of nucleic acids to solid surfaces, wherein an unmodified nucleic acid molecule is coupled to a silane-coated solid phase. The unmodified nucleic acid molecules may be genomic DNA or cDNA. The solid support of the reference may be a microtiter plate. The method of the reference may also comprise the step of capturing from a solution at least one strand of a specific polynucleotide analyte by hybridization to the immobilized nucleic acid molecule and detecting the captured analyte (claim 24 of reference).

16. Claims 1-6, 9, 12-18, and 20 are rejected under 35 U.S.C. 102(b) as being anticipated by Yamane (US Pat. 5,741,638). The reference discloses a microtiter well for detecting a nucleic acid. According to the reference, a single stranded nucleic acid that is specifically hybridizable with a target nucleic acid is immobilized on a microtiter well. Detection of the target analyte occurs after it contacts the immobilized single stranded nucleic acid. The immobilized nucleic acid may be DNA, and the DNA may be irradiated with UV to achieve immobilization (Example 4). When the label used for detection is indirectly detectable, detection of target analyte may be carried out by using an acceptor (such as via the use of an antibody).

17. Claims 1-3, 9, 12-15, and 20 are rejected under 35 U.S.C. 102(b) as being anticipated by Mitsuhashi et al. (US Pat. 5,639,612). The reference discloses methods for detecting polynucleotides with immobilized polynucleotide probes. A solid support such as a microtiter plate with a plurality of wells may be used as the support, wherein each of the wells preferably has a specific polynucleotide probe immobilized thereon. The first probe, which may be

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immobilized on the microtiter plate, is preferably DNA. An antibody may be used to contact the solid phase to facilitate detection of the target analyte.

Claim Rejections - 35 USC § 103

18. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all

obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

19. The factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148 USPQ 459

(1966), that are applied for establishing a background for determining obviousness under 35

U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

20. Claims 10-11 and 21-22 are rejected under 35 U.S.C. 103(a) as being unpatentable over

Giordano et al. (US Pat. 5,705,344). The reference teaches a screening assay for helicase inhibitors, as previously discussed. However, the reference does not teach DNA-PK or anti-DNA-PK antibody.

It would have been prima facie obvious to one of ordinary skill in the art at the time of the invention to detect DNA-PK and use anti-DNA-PK antibodies for this purpose because the selection of the analyte of interest merely represents an optimization of the assay protocol.

Depending on the analyte of interest chosen, one of skill in the art would have known the appropriate antibody to use. It has been held to be within the general skill of a worker in the art

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to select a known material on the basis of its suitability for the intended use as a matter of obvious design choice. *In re Leshin*, 125 USPQ 416.

Conclusion

Claims 1-22 are rejected.

Reference: Skouv is cited as art of interest for teaching a detection method using immobilized nucleic acids.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Kartic Padmanabhan whose telephone number is 703-305-0509. The examiner can normally be reached on M-F (8:30-5:00).

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Long Le can be reached on 703-305-3399. The fax phone numbers for the organization where this application or proceeding is assigned are 703-746-5207 for regular communications and 703-305-3014 for After Final communications.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is 703-308-0196.

Kartic Padmanabhan
Patent Examiner
Art Unit 1641

June 1, 2003


LONG V. LE
SUPERVISORY PATENT EXAMINER
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06/12/03